UNITED STATE DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Case No.: _____

JODI ROUVIERE, Individually and
ANDRE ROUVIERE, her husband, Individually,

Plaintiff

v.

DEPUY ORTHOPAEDICS, INC.,
DEPUY PRODUCTS, INC.,
DEPUY INTERNATIONAL, LIMITED,
JOHNSON & JOHNSON, INC.,
and JOHNSON & JOHNSON SERVICES, INC.,
and STRYKER CORPORATION,
STRYKER SALES CORPORATION, and
HOWMEDICA OSTEONICS CORPORATION,
d/b/aSTRYKER ORTHOPAEDICS

Defendants

_____/

COMPLAINT FOR DAMAGES

Plaintiffs JODI ROUVIERE ("Plaintiff" or "Mrs. Rouviere"), and Plaintiff, ANDRE ROUVIERE, her husband hereby file this complaint and alleges as follows:

I. INTRODUCTION

1. As detailed below, Plaintiffs brings this action for damages for severe and permanent personal injuries including elevated blood levels of chromium, chromium toxicity, elevated blood levels of cobalt, cobalt toxicity, inflammation, pain, swelling, loss of range of motion, surgical removal and revision of hip replacement system, hip explant, pain and suffering, economic loss, and permanent disability, all of which Jodi Rouvire has sustained as a consequence of being implanted with the defendants Depuy' "Summit" total hip arthroplasty system stem (" Summit Tapered Hip System Stem") and defendant Stryker MDM®X3®" ADM/MDM System, "The

Restoration"

2. The Summit Tapered Hip System is a hip replacement system designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold by the defendants DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL, LIMITED, JOHNSON & JOHNSON, INC., and JOHNSON & JOHNSON SERVICES, INC.

3. Numerous adverse event reports regarding the widespread failures of the Summit Tapered Hip System have been filed with the FDA. The Summit Tapered Hip System has injured many people, including Mrs. Rouviere. Moreover, defendants continues market the Summit Tapered Hip System with the same design as the Summit Tapered Hip System implanted in Mrs. Rouviere.

4. The Summit Tapered Hip System, Stem implanted in, and consequently explanted, from Mrs. Rouviere will hereinafter be referred to as the "Depuy subject product."

5. The venue for this action lies in the Southern District of New York.

6. The Depuy subject product Summit was implanted at The Hospital For Special Surgeries, in New York County and within the Southern District of New York, on August 17, 2012. Plaintiff underwent revision surgery to remove the failing Depuy subject product on November 11, 2016 at Baptist Hospital Miami Florida.

7. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System is a hip replacement system designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold by the defendants STRYKER CORPORATION, STRYKER SALES CORPORATION, and HOWMEDICA OSTEONICS CORPORATION, d/b/a STRYKER ORTHOPAEDICS.

8. Numerous adverse event reports regarding the widespread failures of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System have been filed with the FDA. The MDM®X3®" ADM/MDM System has injured many people, including Mrs. Rouviere. Moreover, defendants continues market the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System with the same design as the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System implanted in Mrs. Rouviere.

9 The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System implanted in, and consequently explanted, from Mrs. Rouviere will hereinafter be referred to as the "Stryker subject product."

10. The venue for this action lies in the Southern District of New York.

11. The Stryker subject product was implanted at The Hospital For Special Surgeries, in New York County and within the Southern District of New York, on August 17, 2012. Plaintiff underwent revision surgery to remove the failing Stryker subject product on November 11, 2016 at Baptist Hospital Miami Florida.

12. Venue is appropriate in the Southern District of New York pursuant to 28 U.S.C. § 1391(b)(2).

II. THE PARTIES

13. Plaintiff Jodi Rouviere is a resident of Miami Florida.

14. Plaintiff Andre Rouviere is a resident of Miami Florida.

15. Plaintiff Jodi Rouviere is domiciled in the State of Florida.

16. Plaintiff Andre Rouviere is domiciled in the State of Florida, and at all times, the legal husband of the plaintiff Jodi Rouviere.

17. Plaintiff Jodi Rouviere is a citizen of the State of Floida.

18. Plaintiff Andre Rouviere is a citizen of the State of Floida

19. Defendant DEPUY ORTHOPAEDICS, INC ("DEPUY ORTHOPEDICS") is a corporation existing under the laws of the state of Indiana with its principal place of business in Warsaw, Indiana, 700 Orthopaedic Drive, Warsaw, Indiana 46581.

20. Defendant DEPUY ORTHOPEDICS designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

21. Defendant DEPUY PRODUCTS, INC ("DEPUY PRODUCTS") is a corporation existing under the laws of the state of Indiana with its principal place of business in Warsaw, Indiana, 700 Orthopaedic Drive, Warsaw, Indiana 46581.

22. Defendant DEPUY PRODUCTS designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

23. Defendant, DEPUY INTERNATIONAL, LIMITED ("DEPUY INTERNATIONAL") is a subsidiary of DEPUY ORTHOPAEDICS. DEPUY INTERNATIONAL is a private limited company, as that term is defined by the laws of the United Kingdom, having a principal place of business in Leeds, West Yorkshire, United Kingdom (St. Anthony's Road, Beeston, UK LS11 8DT).

24. Defendant DEPUY INTERNATIONAL designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

25. Defendant JOHNSON & JOHNSON, INC. ("J&J") is a corporation existing under the laws of the state of New Jersey with its principal place of business located at One Johnson

and Johnson Plaza, New Brunswick, New Jersey 08933..

26. Defendant J&J is the parent company of DEPUY ORTHOPAEDICS

27. Defendant J&J, as parent to defendant DEPUY ORTHOPAEDICS, designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

28. Defendant JOHNSON & JOHNSON, SERVICES INC. ("J&J SERVICES") is a corporation existing under the laws of the state of New Jersey with its principal place of business located at One Johnson and Johnson Plaza, New Brunswick, New Jersey 08933.

29. Defendant J&J SERVICES is the parent company of DEPUY ORTHOPAEDICS.

30. Defendant J&J SERVICES, as parent to defendant DEPUY ORTHOPAEDICS, designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

31. Defendants DEPUY ORTHOPAEDICS, DEPUY PRODUCTS, DEPUY INTERNATIONAL, J&J, and J&J SERVICES are referred to collectively as "Defendants."

32. Each of the Defendants is a business engaged in designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the Summit Tapered Hip System.

33. At all times mentioned, each of the Defendants was the representative, agent, employee, joint venture participant, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each defendant was an instrumentality or conduit of the other in the pursuit of the design, promotion, and sale of the Summit Tapered Hip System.

34. Each of the Defendants transacts business in New York State, including in New York County within the Southern District of New York, where Plaintiff received the subject

product, the Summit Tapered Hip System.

35. Defendants assumed responsibility and continue to remain responsible for all legal obligations and liabilities, including personal injury and other tort claims, arising from the design, manufacture, test, inspection, distribution and sale of the Summit Tapered Hip System and stem.

36. Defendant Stryker Corporation is a corporation organized and existing under the laws of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

37. Defendant Stryker Corporation is a resident of the State of Michigan.

38. Defendant Stryker Corporation conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York.

39. At all relevant times, Stryker Corporation developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Defendants' Defective Devices, either directly or indirectly, to members of the general public throughout the United States.

40. At all relevant times, Stryker Corporation was present and doing business in the State of New York and in the Southern District of New York in particular.

41. At all relevant times, Stryker Corporation transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

42. At all relevant times, Stryker Corporation expected or should have expected that its acts would have consequences with within the United States and in the Southern District of New York in particular

43. Defendant Stryker Sales Corporation is corporation organized

and existing uner the laws of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

44. Defendant Stryker Sales Corporation is a resident of the State of Michigan.

45. Defendant Stryker Sales Corporation conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York.

46. Defendant Stryker Sales Corporation conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York.

47. At all relevant times, Stryker Sales Corporation developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Defendants' Defective Devices, either directly or indirectly, to members of the general public throughout the United States.

48. At all relevant times, Stryker Sales Corporation was present and doing business in the State of New York and in the Southern District of New York in particular.

49. At all relevant times, Stryker Sales Corporation transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

50. At all times, Stryker Sales Corporation expected or should have expected that its acts would have consequences within the United States and in the Southern District of New York in particular.

51. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics, is a corporation organized and existing under the laws of New Jersey having its principal place of

business located at 325 Corporate Drive, Mahwah, New Jersey 07430.

52. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics is a resident

of the State of New Jersey.

53. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York and in the Southern District of New York.

54. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Defendants' Defective Devices, either directly or indirectly, to members of the general public throughout the United States

55. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics was present and doing business in the State of New York and in the Southern District of New York in particular.

56. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

57. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics expected or should have expected that its acts would have consequences within the United States, and in the Southern District of New York in particular.

58. At all relevant times, the employees of STRYKER CORPORATION, STRYKER SALES CORPORATION, and HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS (hereinafter "Defendants") and each of them, their subsidiaries, affiliates, and other related entities, as well as the employees of the defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment.

Whenever reference in this Complaint is made to any act or transaction of defendants STRYKER, such designations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the defendants, and each of them, committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of defendants while actively engaged in the scope of their duties.

59. At all relevant times, each of the defendants were present and doing business in the State of New York in the Southern District of New York.

60. At all relevant times, each of the defendants transacted, solicited, and conducted business in the State of New York. and derived substantial revenue from such business.

61. At all relevant times, each of the defendants expected or should have expected that its acts would have consequences within the United States, and in the Southern District of New York in particular.

III. JURISDICTION AND VENUE

62. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, as more fully set forth above, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

63. This Court has supplemental jurisdiction over the common law and state claims pursuant to 28 U.S.C. § 1367.

64. Plaintiffs reside in the State of Florida.

65. Plaintiffs are domiciled in the State of Florida.

66. Plaintiffs are citizens of the State of Florida.

67. No Defendant is a citizen of the same state as Plaintiffs.

68. The subject products were implanted in New York County, New York State.

69. Venue is proper in this district pursuant to 28 U.S.C. §1961, *et seq*. because a substantial part of the events giving rise to this claim occurred in New York and this district.

70. DEPUY Defendants are large companies, transacting and conducting business in

the State of New York, including in the Southern District, by designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the Summit Tapered Hip System by Defendants supply the Summit Tapered Hip System to New York surgeons, hospitals and, of course, to the patients of those surgeons and hospitals.

71. STRYKER Defendants are large companies, transacting and conducting business in the State of New York, including in the Southern District, by designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System by Defendants supply the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System to New York surgeons, hospitals and, of course, to the patients of those surgeons and hospitals.

72. Defendants expected or should have expected that their acts would have consequences within the Southern District of New York, and derived substantial revenue from interstate commerce.

73. Defendants are further subject to *in personam* jurisdiction in the United States District Court for the Southern District of New York because they placed defective products in the stream of commerce there and the subject product was implanted there.

IV. FACTUAL BACKGROUND

74. At all times mentioned in this complaint, the Depuy Defendants designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold a hip replacement system, defective in its design, defective in its warnings, and defective in its manufacture, known as the Summit Tapered Hip System. The Summit Tapered Hip System was sold to surgeons and hospitals in New York State and elsewhere, and implanted in thousands of patients, including Plaintiff.

75. At all times mentioned in this complaint, the STRYKER Defendants designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold a hip replacement system, defective in its design, defective in its warnings, and defective in its manufacture, known as the "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System was sold to surgeons and hospitals in New York State and elsewhere, and implanted in thousands of patients, including Plaintiff.

76. At all times material, the Depuy Defendants owed a duty to the Plaintiff to assure that its product would be implanted in a medically safe manner including the use of all its own hip system parts.

77. At all times material, the DEPUY defendants knew or should have known that surgeons, including but not limited to Dr. Robert Buly, would mix and match components of various hip systems with other hip systems. The defendant failed to maintain accurate and reliable inventory and records that would have allowed the defendant to track the sales to particular hospitals and doctors and permit the tracking of uneven numbers of components of their hip system being used by hospitals thus preventing the tracking of the disproportionate use of the components of a particular hip system due to mixing and matching including the Depuy Summit Tapered Hip System.

78. At all times material , the Depuy defendants failed to provide adequate warning and or supervision of surgeons implanting these hip components and failed to establish an appropriate monitoring system to track the stock and inventory so that mix and match of different hip systems would and could not occur.

79. At all times material, the Stryker defendants owed a duty to the Plaintiff to assure that its product would be implanted in a medically safe manner including the use of all its own hip system parts.

80. At all times material, the Stryker defendants knew or should have known that

surgeons, including but not limited to Dr. Robert Buly, would mix and match components of various hip systems with other hip systems. the defendant failed to maintain accurate and reliable inventory and records that would have allowed the defendant to track the sales to particular hospitals and doctors and permit the tracking of uneven numbers of components of their hip system being used by hospitals thus preventing the tracking of the disproportionate use of the components of a particular hip system due to missing and matching including the Stryker "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System.

81. At all times material , the Stryker defendants failed to provide adequate warning and or supervision of surgeons implanting these hip components and failed to establish an appropriate monitoring system to track the stock and inventory so that mix and match of different hip systems would and could not occur.

THE SUMMIT TAPERED HIP SYSTEM

82. First marketed and sold prior to 2012, Defendants developed the Summit Tapered Hip System in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture. The hip joint connects the thigh or femur bone of the leg to the pelvis. The hip joint resembles a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

83. The Summit total hip replacement implant device consists of four separate components: a femoral stem; a femoral head or ball; a liner; and an acetabular shell or socket. The Stryker MDM consists of four separate parts. In Plaintiffs total hip replacement the femoral stem was the Depuy Summit stem un cemented stem size #1 high offset 125mm component; the Head was a Depuy Biolox delta art cam HD 28+5 mm,

along with *"a Stryker acetabular* shell HA cluster hemi 52mm***; Stryker*** ADM x3***28/48 polyethalene insert.."* (Source: Operative Report of Index Surgery).**

84. Defendants marketed and described the Summit Device as "uniquely designed to meet the demands of active patients like you - and help reduce pain".

85. Defendants advertised and sold the Summit Device as the best surgical option that *"recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."*

86. Defendants sold over 100,000 Summit Devices. Defendants stated in Promotional materials that "99.9% of Summit hip components are still in use today."

87. Over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failure or complications of the Summit Devices.

88. Defendants have long been aware, including before Plaintiff's receipt of her Summit , that Summit Devices may result in metallosis, biologic toxicity and high failure rate. The Summit Device, when implanted, results unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiff further alleges that Defendants were and continue to be aware that the metal particles from Summit Devices results in metallosis tissue death, bone erosion

89. Plaintiff alleges that particulate debris from the Summit Devices causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

90. Plaintiff further alleges that, at all relevant times, Defendants were and continue to be aware that Summit Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

91. Plaintiff was a recipient of a hip replacement with the Summit Device stem, and has suffered permanent injuries, pain and suffering, economic loss and disability.

92. The Summit Device consists of four discrete parts or components that connect: **a metal femoral stem**; a polymel femoral head ("ball"); a liner (half dome shaped and made of cobalt/chromium); and a "cup" that fits into the acetabulum, the so-called "socket" of the hip.

DEFENDANTS DEPUY CLEARED SUMMIT TAPERED HIP SYSTEM AS A CLASS II DEVICE WITHOUT PRE MARKET APPROVAL

93. In 1976, the Medical Devices Amendment ("MDA") was enacted, pursuant to which the United States Food and Drug Administration ("FDA") has classified medical devices into three categories. A Class I category device poses almost no safety issues. A Class II category device poses moderate safety issues. A Class III device operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses potentially unreasonable risks of harm to patients.

94. Generally, Class III devices must undergo the Premarket Approval (PMA) process to be marketed in the United States. Premarket Approval is a rigorous review process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, extensive clinical data to support the device's safety and effectiveness; a full statement of the device's components, ingredients, and properties, and principles of operation; a full description of the methods used in, and the facilities and controls used for, the design, manufacture, processing, and when relevant, packing and installation of such device; samples or device components required

by the FDA; and a specimen of the proposed labeling. When undergoing Premarket Approval, a Class III device may not use an existing device as a predicate. Rather, the safety and effectiveness of the device must be independently shown.

95. As the United States Supreme Court describes it, Premarket Approval is a "rigorous" process. A manufacturer must submit what is typically a multi volume application. *See*, *FDA, Device Advice--Premarket Approval (PMA) 18*, http://www.fda.gov/cdrhldevadvice/pma!printer.htm. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 U.S.C. §360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts. 21 C.F.R. § 814.44(a) (2007). The panel may request additional data from the manufacturer. 21 U.S.C. § 360e(c)(I)(G). The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-318 (2008). The FDA may grant Premarket Approval only upon a finding that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

96. However devices were formally classified into Class III . Nonetheless, because these Class III devices predate the MDA, and because the FDA has neither called for Pre market

Approval to be requested nor downwardly classified these devices, these hip systems avoided the rigorous scrutiny of the Pre market Approval Process. Instead, they were and are "grandfathered in" and cleared for sale through manufacturers' demonstration of substantial equivalence to other "predicate" systems already on the market. This is the Premarket Notification or "510(k) process" by which Class II devices, ostensibly less dangerous, are cleared for market.

97. The Summit Tapered Hip System and which is the subject of this lawsuit should have undergone the Premarket Approval process for Class III medical devices.

98. However, Defendants received clearance of the Summit Tapered Hip System from the FDA through the 510(k) process which is generally reserved for Class II devices. The 510(k) process only requires a showing of substantial equivalence to a device already on the market. The FDA spends approximately twenty hours on this review process. *See, Adesina v. Aladan Corp.*, 438 F.Supp.2d 329, 334 (S.D.N.Y. 2006).

99. In obtaining clearance for marketing of the Summit Tapered Hip System through the 510(k) process, Defendants made an end run around and bypassed the rigorous Premarket Approval process altogether.

100. The Summit Tapered Hip System did not receive Premarket Approval from the FDA.

101. The Defendants did not seek Pre-Market Approval from the FDA for the Summit System.

102. The Defendants conducted no clinical trials of the Summit Device before first marketing and selling it in the early part of last decade.

103. Clinical trials, if performed, would have demonstrated that Summit Device recipients developed metallosis and experienced failure of their hip replacements at a higher than expected rate, one exceeding acceptable rates in the industry. The trials would have also demonstrated a higher than expected, and unreasonably dangerous, incidence of elevated blood

metal levels. The human body, for example, should not have any measurable cobalt ions in the blood.

104. The Summit Device is unreasonably dangerous in that its cobalt and chromium components, the femoral head and the liner, interface. The resulting friction from ordinary and expected usage of the device, such as walking, causes "fretting" and the release of metal particles.

105. The release of cobalt and chromium particles results in pain, swelling, inflammation, adverse tissue reactions, metallosis, necrosis of bone, muscle and other tissues, with a decrease in range of motion.

106. The performance of the Summit Device is akin to other predecessor hip systems that have been recalled globally, for reasons substantially similar to the hazards of the Summit

107. The devices share more than shoddy performance.

108. The FDA has received over 1,300 adverse reports concerning the Summit Device.

109. In 1996, Jonathan Black, Ph.D., an industry consultant and Clemson University professor emeritus of bioengineering specializing in production and biological sequelae of wear debris, warned in a medical journal article that these hip designs posed significant risks because little was known of the biological damage that metallic debris might cause. Dr. Black also argued that, given the high success rate of existing designs, it would be statistically impossible to run enough studies to prove the new implants' supposed superiority.

110. On November 1, 2001, in *The Journal of Bone and Joint Surgery* 83:S68-72, Dr. Seth Greenwald and Dr. Jonathan Garino echoed Professor Black's concerns regarding the long term effects of metal particle and ion generation, citing increased chromium concentrations found in McKee-Farrar implant recipients who were followed in multiyear studies.

111. In 2003, the *British Journal of Bone and Joint Surgery* reported the work of Clarke, Lee, Arora and Villar who found that large diameter metal-on-metal bearings result in greater systemic exposure of the device recipients to cobalt and chromium ions.

112. In July 2005, *The Journal of Bone and Joint Surgery* published the results of a

study that retrospectively analyzed 165 patients (169 hips) who had undergone primary cementless total hip replacement with contemporaryl total hip replacement designs. The findings of the study raised concern that early osteolysis in patients with second generation hip replacement systems is associated with abnormalities consistent with delayed-type metal hypersensitivities.

113. The formation of metallosis, pseudotumors, infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility. These formations further render revision surgery exponentially more difficult to perform.

114. At all relevant times, Defendants were aware that the Summit Tapered Hip System stem posed an unreasonably high risk of causing metallosis, biologic toxicity, and total hip failure. Defendants were aware that the Summit Tapered Hip System resulted in unsafe release of toxic metal ions into the tissues and bloodstream of the recipients.

DEFENDANTS STRYKER CLEARED " THE "MDM®X3®" ADM/MDM SYSTEM, "THE RESTORATION®" ADM/MDM SYSTEM AS A CLASS II DEVICE WITHOUT PRE MARKET APPROVAL

115. In 1976, the Medical Devices Amendment ("MDA") was enacted, pursuant to which the United States Food and Drug Administration ("FDA") has classified medical devices into three categories. A Class I category device poses almost no safety issues. A Class II category device poses moderate safety issues. A Class III device operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses potentially unreasonable risks of harm to patients.

116. Generally, Class III devices must undergo the Premarket Approval (PMA) process to be marketed in the United States. Premarket Approval is a rigorous review process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, extensive clinical data to support the device's safety and effectiveness; a full statement of the device's components, ingredients, and properties, and principles of operation; a full

description of the methods used in, and the facilities and controls used for, the design, manufacture, processing, and when relevant, packing and installation of such device; samples or device components required by the FDA; and a specimen of the proposed labeling. When undergoing Premarket Approval, a Class III device may not use an existing device as a predicate. Rather, the safety and effectiveness of the device must be independently shown.

117. As the United States Supreme Court describes it, Premarket Approval is a "rigorous" process. A manufacturer must submit what is typically a multivolume application. *See, FDA, Device Advice--Premarket Approval (PMA) 18*, http://www.fda.gov/cdrhldevadvice/pma!printer.htm. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 U.S.C. §360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts. 21 C.F.R. § 814.44(a) (2007). The panel may request additional data from the manufacturer. 21 U.S.C. § 360e(c)(I)(G). The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-318 (2008). The FDA may grant Premarket Approval only upon a finding that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

118. Nonetheless, because these Class III devices predate the MDA, and because the FDA has neither called for Pre market Approval to be requested nor downwardly classified these devices, metal-on-metal hip systems avoided the rigorous scrutiny of the Pre market Approval Process. Instead, they were and are "grandfathered in" and cleared for sale through manufacturers' demonstration of substantial equivalence to other "predicate" systems already on the market. This is the Premarket Notification or "510(k) process" by which Class II devices, ostensibly less dangerous, are cleared for market.

119. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System which is the subject of this lawsuit should have undergone the Premarket Approval process for Class III medical devices.

120. However, Defendants received clearance of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System from the FDA through the 510(k) process which is generally reserved for Class II devices. The 510(k) process only requires a showing of substantial equivalence to a device already on the market. The FDA spends approximately twenty hours on this review process. *See, Adesina v. Aladan Corp.*, 438 F.Supp.2d 329, 334 (S.D.N.Y. 2006).

121. In obtaining clearance for marketing of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System through the 510(k) process, Defendants made an end run around and bypassed the rigorous Premarket Approval process altogether.

122. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System did not receive Premarket Approval from the FDA.

123. The Defendants did not seek Pre-Market Approval from the FDA for the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

124. The Defendants conducted no clinical trials of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System before first marketing

and selling it in the early part of this decade (2011).

125. Clinical trials, if performed, would have demonstrated that "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System Device recipients developed metallosis and experienced failure of their hip replacements at a higher than expected rate, one exceeding acceptable rates in the industry. The trials would have also demonstrated a higher than expected, and unreasonably dangerous, incidence of elevated blood metal levels. The human body, for example, should not have any measurable cobalt ions in the blood.

126. The " The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System is unreasonably dangerous in that its cobalt and chromium components, the femoral head and the liner, interface. The resulting friction from ordinary and expected usage of the device, such as walking, causes "fretting" and the release of metal particles.

127. The release of cobalt and chromium particles results in pain, swelling, inflammation, adverse tissue reactions, metallosis, necrosis of bone, muscle and other tissues, with a decrease in range of motion.

128. The formation of metallosis, pseudotumors, infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility. These formations further render revision surgery exponentially more difficult to perform.

129. At all relevant times, Defendants were aware that the " The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System posed an unreasonably high risk of causing metallosis, biologic toxicity, and total hip failure. Defendants were aware that the " The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System resulted in unsafe release of toxic metal ions into the tissues and bloodstream of the recipients.

THE FAILURE OF PLAINTIFF'S SUMMIT DEVICE

130. Mrs. Rouviere suffers from degenerative joint disease in her left hip.

131. On August 12, 2012, Plaintiff underwent a total right hip replacement at New Yorks Hospital for Special Surgery . Robert Buly, M.D., an orthopedic surgeon, performed the surgery. He implanted a Summit Tapered Hip System Stem into plaintiffs right hip.

132. Dr. Buly implanted the subject product in accordance with instructions, directions and other information made available by the Defendants, the manufacturers and designers.

133. Plaintiff followed all post-operative instructions from her physicians, and made continued improvements in her ability to walk, move her right leg, and regain range of motion.

134. Post-operatively, Ms. Rouviere's Summit Tapered Hip System stem failed. by the beginning of 2013, she experienced pain and loss of range of motion.

135. Blood testing performed in May, 2015 demonstrated highly elevated Chromium level of .9 MUG/L , Arsenic of MUG/L 5 and cobalt was not tested for at that time, and in December 2016 , one month after the removal of the defective hip the Cobalt level was .6 MCG/L and chromium was < .2 MCG/L.

136. Mrs. Rouviere underwent revision surgery on November 11, 2016. The diagnosis given by the Dr Carlos Alvarado, MD was *"ASEPTIC INFLAMMATORY FAILURE, RIGHT HIP ARTHROPLASTY."*

137. *"Black metallic prosthetic particles"* were ascertained by pathology studies of excised tissue.

138. Plaintiff's Summit Tapered Hip System stem deteriorated, released and releases metals, including cobalt from its surface.

139. Plaintiff's Summit Tapered Hip System stem deteriorated, and released and releases cobalt from its interior.

140. Plaintiff's Summit Tapered Hip System stem deteriorated, and released and releases chromium from its surfaces.

141. Plaintiff's Summit Tapered Hip System stem deteriorated, and released and

releases chromium from its interior.

142. . Plaintiff's elevated blood levels of cobalt resulted directly from the deterioration of the Summit Tapered Hip System stem.

143. Plaintiff's elevated blood levels of chromium resulted directly from the deterioration of Summit Tapered Hip System stem.

144. The U.S. Department of Health and Human Services/Agency for Toxic Substances and Diseases Registry ("ATSDR") issues toxicological profiles for cobalt and chromium.

145. According to the ATSDR, absorption of excess cobalt results in effects to the respiratory, cardiovascular, gastrointestinal, hematological, hepatic, renal, endocrine, dermal, and ocular systems. Cardiomyopathy, damage to nerves, and dysfunctional blood clotting may result.

146. According to the ATSDR, absorption of excess chromium results in renal failure, hemolysis, liver damage, multiple organ failure and death.

147. Plaintiff does not suffer and has not suffered from occupational exposure to cobalt.

148. Plaintiff does not suffer and has not suffered from occupational exposure to chromium.

149. Plaintiff does not ingest and has not ingested, orally or through inhalation, cobalt.

150. Plaintiff does not ingest and has not ingested, orally or through inhalation, chromium.

151. Plaintiff has no source of exposure to cobalt that would account for her elevated blood levels of cobalt other than the subject product.

152. Plaintiff has no source of exposure to chromium that would account for her elevated blood levels of chromium other than the subject product.

153. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not release cobalt into the human body.

154. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not release chromium into the human body.

155. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely and release cobalt into the human body.

156. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely and release chromium into the human body.

157. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not deteriorate prematurely and release cobalt into the human body.

158. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not deteriorate prematurely and release chromium into the human body.

159. Unreasonably dangerous hip implants, as manufactured, will deteriorate prematurely and release cobalt into the human body.

160. Unreasonably dangerous hip implants, as manufactured, will deteriorate prematurely and release chromium into the human body.

161. The Defendants' Summit Tapered Hip System Stem was unreasonably dangerous in design in that it deteriorated prematurely and released and releases cobalt into the human body, including Plaintiff's body.

162. The Defendants' Summit Tapered Hip System stem was unreasonably dangerous in design in that it deteriorated prematurely and released and releases chromium into the human body, including Plaintiff's body.

163. The Defendants' Summit Tapered Hip System stem was unreasonably dangerous in manufacture in that it deteriorated prematurely and released and releases cobalt into the human body, including Plaintiff's body.

164. The Defendants' Summit Tapered Hip System stem was unreasonably dangerous in manufacture in that it deteriorated prematurely and released and releases chromium into

the human body, including Plaintiff's body.

165. Defendants' Summit Tapered Hip System Stem deteriorated with usage under normal, ordinary and foreseeable conditions, resulting in the release of cobalt and chromium into the surrounding tissue, blood and organs of the recipient.

166. As manufacturers of hip replacement systems, the Defendants had the legal duty to warn physicians of the risk of deterioration of the Summit Tapered Hip System stem, the risk that the Summit Tapered Hip System's stem composition, including chromium and cobalt, would deteriorate and release cobalt and chromium into the surrounding tissue, blood, and organs of the patient.

167. The Summit Tapered Hip System stem came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

168. The Summit Tapered Hip System stem came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of chromium from its component parts.

169. The Summit Tapered Hip System stem came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in deterioration and in elevated cobalt levels in the human body.

170. The Summit Tapered Hip System stem came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in deterioration and in elevated chromium levels in the human body.

171. The Summit Tapered Hip System stem came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its deterioration and the release of cobalt from its component parts.

172. The Summit Tapered Hip System stem came with no written information

that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its deterioration and the release of chromium from its component parts.

173. The Summit Tapered Hip System stem came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be deterioration with resulting elevated cobalt levels in the human body.

174. The Summit Tapered Hip System stem came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be elevated chromium levels in the human body.

175. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the Summit Tapered Hip System stem and its component parts had they known that it usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

176. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the Summit Tapered Hip System stem and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of chromium from its component parts.

177. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the Summit Tapered Hip System stem and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in deterioration and elevated levels of cobalt in patients receiving the implant.

178. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the Summit Tapered Hip System stem and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in deterioration and elevated levels of chromium in patients receiving the implant.

179. Defendants failed to advise Plaintiff's implanting surgeon that the usage of System stem under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

180. Defendants failed to advise Plaintiff's implanting surgeon that the usage of System under normal, ordinary and foreseeable conditions would result in deterioration and the release of chromium from its component parts.

181. Defendants failed to advise Plaintiff's implanting surgeon that the usage of Summit System under normal, ordinary and foreseeable conditions would result in elevated cobalt levels in the human body.

182. Defendants failed to advise Plaintiff's implanting surgeon that the usage of Summit System stem under normal, ordinary and foreseeable conditions would result in elevated chromium levels in the human body.

183. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem had he known that its usage under normal, ordinary and foreseeable conditions would result in the release of cobalt from its component parts.

184. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in the release of chromium from its component parts.

185. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in elevated levels of cobalt in patients receiving the implant, including Plaintiff.

186. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in elevated levels of chromium in patients receiving the implant, including, Plaintiff Mrs. Rouviere.

187. The FDA panel did not find that the Summit systems provided significant benefits to the thousands of American patients who rely on them.

188. Defendants did not have adequate and appropriate systems in place to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the Summit Tapered Hip System stem, as required by the FDA, thus leading to inconsistencies and irregularities in the way defendants kept track of complaints they received regarding the failure of the Summit System.

189. Defendants knew, or should have known, of the seriousness of the risks of using the Summit Tapered Hip System stem, based upon the state of knowledge of the Summit Tapered Hip System, as it existed at that time, and upon generally accepted medical and research standards and principles.

190. Defendants knew, or should have known, of the seriousness of the risks of using the Summit Tapered Hip System stem based upon the complaints they received from doctors, hospitals, and/or patients who used the Summit Tapered Hip System demonstrating that the product was defective.

191. Defendants failed to send the necessary product failure reports to the FDA, as required by the FDA, indicating that the failure rate of Summit Tapered Hip System and its stem was higher than the generally accepted standard rate of failure in the industry.

192. Defendants failed to appropriately and adequately warn the Plaintiff and her physicians, hospitals, and/or the FDA, of the serious and dangerous risks involved in using Defendants'

Summit Tapered Hip System including, but not limited to, severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

193. Defendants misrepresented the known risks inherent in the use of the Summit Tapered Hip System and its stem.

194. Defendants made certain claims which were distributed and circulated to the medical and healthcare professions that the Summit Tapered Hip System and its stem were safe.

195. Defendants were careless and negligent in the manufacturing, testing, selling, distribution, merchandising, advertising, marketing, promotion, compounding, packaging, fabrication, warning, analyzing, marketing, and recommendation of the Summit Tapered Hip System and its stem.

196. By reason of the foregoing, Plaintiff has suffered and/or is at an extremely high risk of suffering serious and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

197. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects as a result of her Summit Tapered Hip System and its stem. Plaintiff suffers from elevated blood metal levels and has had to undergo surgical explanation of her prosthetic hip and/or components. The plaintiff lives without one hip.

198. By reason of the foregoing, Plaintiff has been severely and permanently injured and/or has been exposed to risk of severe and permanent injury, and will require more constant and continuous medical monitoring and treatment than prior to her implantation of Defendants' Summit Tapered Hip System and its stem..

199. Moreover, "Medical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements). 21 U.S.C.

§ 360j(f); 21 C.F.R. § 820 *et seq.* These requirements set forth a quality control system and "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R § 820.1(a)(1). They are in place "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1). To comply with the CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective." *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 279 (E.D.N.Y. 2009), *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 152 (S.D.N.Y. 2011).

200. In designing, developing, testing, manufacturing, assembling, packaging, promoting, labeling, marketing, distributing and selling the Summit Tapered Hip System, and stem Defendants violated CGMP requirements for the reasons set forth above, including the deterioration of the metal stem.

201. Defendants knowingly and deliberately made material misrepresentations to the FDA concerning the design, manufacture, safety, and efficacy of Defendants' Summit Tapered Hip System and its stemwas a Section 510(k) medical device.

202. Defendants' claims to the FDA, that Defendants' Summit Tapered Hip

System and its stem was substantially equivalent to predicate devices marketed prior to May 28, 1976, misled the FDA and the consuming public.

203. By marketing Defendants' Summit Tapered Hip System and its stem, as Section 510(k) medical device, Defendants were able to avoid conducting any formal review or undertaking any study of the products' safety or efficacy.

204. Defendants' Summit Tapered Hip System and its stem was designed, patented, manufactured, labeled, marketed, and sold and distributed by Defendants, at all times relevant herein to the medical community and to patients as: safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of patients undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of osteoarthritis and other conditions and/or diseases; and as safer and more effective as compared to the traditional products and procedures for treatment and other competing products.

205. Mrs. Rouviere suffers from degenerative joint disease in her left hip.

206. On August 12, 2012, Plaintiff underwent a total right hip replacement at New Yorks Hospital for Special Surgery . Robert Buly, M.D., an orthopedic surgeon, performed the surgery. He implanted a "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System Stem into plaintiffs right hip.

207. Dr. Buly implanted the subject product in accordance with instructions, directions and other information made available by the Defendants, the manufacturers and designers.

208. Plaintiff followed all post-operative instructions from her physicians, and made continued improvements in her ability to walk, move her right leg, and regain range of motion.

209. Post-operatively, Ms. Rouviere's "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System failed. by the beginning of 2013, she experienced pain and loss of range of motion.

210. Blood testing performed in May, 2015 demonstrated highly elevated Chromium level of .9 MUG/L , Arsenic of MUG/L 5 and cobalt was not tested for at that time, and in December 2016 , one month after the removal of the defective hip the Cobalt level was .6 MCG/L and chromium was < .2 MCG/L.

211. Mrs. Rouviere underwent revision surgery on November 11, 2016. The diagnosis given by the Dr Carlos Alvarado, MD was *"ASEPTIC INFLAMMATORY FAILURE, RIGHT HIP ARTHROPLASTY."*

212. *"Black metallic prosthetic particles"* were ascertained by pathology studies of excised tissue.

213. Plaintiff's "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, released and releases metals, including cobalt from its surface.

214. Plaintiff's "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, and released and releases cobalt from its interior.

215. Plaintiff's "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, and released and releases chromium from its surfaces.

216. Plaintiff's "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, and released and releases chromium from its interior.

217. Plaintiff's elevated blood levels of cobalt resulted directly from the deterioration of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

218. Plaintiff's elevated blood levels of chromium resulted directly from the deterioration of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System stem.

219. The U.S. Department of Health and Human Services/Agency for Toxic Substances and Diseases Registry ("ATSDR") issues toxicological profiles for cobalt and chromium.

220. According to the ATSDR, absorption of excess cobalt results in effects to the

respiratory, cardiovascular, gastrointestinal, hematological, hepatic, renal, endocrine, dermal, and ocular systems. Cardiomyopathy, damage to nerves, and dysfunctional blood clotting may result.

221. According to the ATSDR, absorption of excess chromium results in renal failure, hemolysis, liver damage, multiple organ failure and death.

222. Plaintiff does not suffer and has not suffered from occupational exposure to cobalt.

223. Plaintiff does not suffer and has not suffered from occupational exposure to chromium.

224. Plaintiff does not ingest and has not ingested, orally or through inhalation, cobalt.

225. Plaintiff does not ingest and has not ingested, orally or through inhalation, chromium.

226. Plaintiff has no source of exposure to cobalt that would account for her elevated blood levels of cobalt other than the subject product.

227. Plaintiff has no source of exposure to chromium that would account for her elevated blood levels of chromium other than the subject product.

228. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not release cobalt into the human body.

229. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not release chromium into the human body.

230. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely and release cobalt into the human body.

231. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely and release chromium into the human body.

232. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not deteriorate prematurely and release cobalt into the human body.

233. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not deteriorate prematurely and release chromium into the human body.

234. Unreasonably dangerous hip implants, as manufactured, will deteriorate prematurely and release cobalt into the human body.

235. Unreasonably dangerous hip implants, as manufactured, will deteriorate prematurely and release chromium into the human body.

236. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in design in that it deteriorated prematurely and released and releases cobalt into the human body, including Plaintiff's body.

237. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in design in that it deteriorated prematurely and released and releases chromium into the human body, including Plaintiff's body.

238. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in manufacture in that it deteriorated prematurely and released and releases cobalt into the human body, including Plaintiff's body.

239. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in manufacture in that it deteriorated prematurely and released and releases chromium into the human body, including Plaintiff's body.

240. Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated with usage under normal, ordinary and foreseeable conditions, resulting in the release of cobalt and chromium into the surrounding tissue, blood and organs of the recipient.

241. As manufacturers of hip replacement systems, the Defendants had the legal duty to warn physicians of the risk of deterioration of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , the risk that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System composition, including chromium and cobalt, would

deteriorate and release cobalt and chromium into the surrounding tissue, blood, and organs of the patient.

242. The "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

243. The "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of chromium from its component parts.

244. The "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in deterioration and in elevated cobalt levels in the human body.

245. The "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in deterioration and in elevated chromium levels in the human body.

246. The "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its deterioration and the release of cobalt from its component parts.

247. The "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its deterioration and the release of chromium from its component parts.

248. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be deterioration with resulting elevated cobalt levels in the human body.

249. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be elevated chromium levels in the human body.

250. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that it usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

251. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in deterioration and the release of chromium from its component parts.

252. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in deterioration and elevated levels of cobalt in patients receiving the implant.

253. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in deterioration and elevated levels of chromium in patients receiving the

implant.

254. Defendants failed to advise Plaintiff's implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

255. Defendants failed to advise Plaintiff's implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in deterioration and the release of chromium from its component parts.

256. Defendants failed to advise Plaintiff's implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in elevated cobalt levels in the human body.

257. Defendants failed to advise Plaintiff's implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in elevated chromium levels in the human body.

258. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System had he known that its usage under normal, ordinary and foreseeable conditions would result in the release of cobalt from its component parts.

259. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in the release of chromium from its component parts.

260. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in elevated levels of cobalt in

patients receiving the implant, including Plaintiff.

261. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in elevated levels of chromium in patients receiving the implant, including, Plaintiff Mrs. Rouviere.

262. Defendants did not have adequate and appropriate systems in place to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , as required by the FDA, thus leading to inconsistencies and irregularities in the way defendants kept track of complaints they received regarding the failure of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

263. Defendants knew, or should have known, of the seriousness of the risks of using the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , based upon the state of knowledge of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , as it existed at that time, and upon generally accepted medical and research standards and principles.

264. Defendants knew, or should have known, of the seriousness of the risks of using the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System based upon the complaints they received from doctors, hospitals, and/or patients who used the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System demonstrating that the product was defective.

265. Defendants failed to send the necessary product failure reports to the FDA, as required by the FDA, indicating that the failure rate of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was higher than the generally accepted standard rate of failure

in the industry.

266. Defendants failed to appropriately and adequately warn the Plaintiff and her physicians, hospitals, and/or the FDA, of the serious and dangerous risks involved in using Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System including, but not limited to, severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

267. Defendants misrepresented the known risks inherent in the use of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

268. Defendants made certain claims which were distributed and circulated to the medical and healthcare professions that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were safe.

269. Defendants were careless and negligent in the manufacturing, testing, selling, distribution, merchandising, advertising, marketing, promotion, compounding, packaging, fabrication, warning, analyzing, marketing, and recommendation of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

270. By reason of the foregoing, Plaintiff has suffered and/or is at an extremely high of suffering serious and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

271. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects as a result of her "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System . Plaintiff suffers from elevated blood metal levels and has had to undergo surgical explanation of her prosthetic hip and/or components. The plaintiff now lives without any right hip.

272. By reason of the foregoing, Plaintiff has been severely and permanently injured

and/or has been exposed to risk of severe and permanent injury, and will require more constant and continuous medical monitoring and treatment than prior to her implantation of Defendants' "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System.

273. Moreover, "Medical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements). 21 U.S.C. § 360j(f); 21 C.F.R. § 820 *et seq.* These requirements set forth a quality control system and "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R § 820.1(a)(1). They are in place "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1). To comply with the CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective." *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 279 (E.D.N.Y. 2009), *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 152 (S.D.N.Y. 2011).

274. In designing, developing, testing, manufacturing, assembling, packaging, promoting, labeling, marketing, distributing and selling the "MDM®X3®," ADM/MDM System, "The Restoration®," ADM/MDM System Defendants violated CGMP requirements for the reasons set

forth above.

275. Defendants knowingly and deliberately made material misrepresentations to the FDA concerning the design, manufacture, safety, and efficacy of Defendants' "MDM®X3®," ADM/MDM System, "The Restoration®" ADM/MDM System was a Section 510(k) medical device.

276. Defendants' claims to the FDA, that Defendants'"MDM®X3®," ADM/MDM System, "The Restoration®" ADM/MDM System was substantially equivalent to predicate devices marketed prior to May 28, 1976, misled the FDA and the consuming public.

277. By marketing Defendants' "MDM®X3®," ADM/MDM System, "The Restoration®" ADM/MDM System , as Section 510(k) medical device, Defendants were able to avoid conducting any formal review or undertaking any study of the products' safety or efficacy.

278. Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was designed, patented, manufactured, labeled, marketed, and sold and distributed by Defendants, at all times relevant herein to the medical community and to patients as: safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of patients undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of osteoarthritis and other conditions and/or diseases; and as safer and more effective as compared to the traditional products and procedures for treatment and other competing products.

FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS DEPUY (NEGLIGENCE AND NEGLIGENCE PER SE)

279. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

280. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, supplying, promoting, packaging, sale and/or distribution of the Summit Tapered Hip System and Stem into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

281. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the Summit Tapered Hip System and its stem into the interstate commerce in that Defendants knew or should have known that using the Summit Tapered Hip System and its stem created a high risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

282. The negligence of the defendants, their agents, servants, and/or employees,

included but was not limited to the following acts and/or omissions:

(a) Designing and manufacturing the Summit Tapered Hip System and its stem without thoroughly testing it;

(b) Not conducting sufficient testing programs to determine whether or not the aforesaid Summit Tapered Hip System and its stem was safe for use; in that defendants knew or should have known that the Summit Tapered Hip System and its stem was unsafe and unfit for use by reason of the dangers to recipients;

(c) Selling the Summit Tapered Hip System and its stem without making proper and sufficient tests to determine the dangers to recipients;

(d) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of the Summit Tapered Hip System and its stem;

(e) Negligently failing to recall their dangerous and defective Summit Systems at the earliest date that it became known that said systems were, in fact, dangerous and defective;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the Summit Tapered Hip System and its stem;

(g) Failing to test the Summit Tapered Hip System and/or failing to adequately, sufficiently and properly test the Summit Tapered Hip System and its stem;

(h) Negligently advertising and recommending the use of the aforesaid Summit Tapered Hip System and its stem without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that the Summit Tapered Hip System and its stem were safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that the Summit Tapered Hip System and its stem had equivalent safety and efficacy as other, non defective total hip replacement systems;

(k) Negligently designing the Summit Tapered Hip System and its stem in a manner which was dangerous to its recipients;

(l) Negligently manufacturing the Summit Tapered Hip System and its stem in a manner which was dangerous to its recipients;

(m) Negligently producing the Summit Tapered Hip System in a manner which was dangerous to its users;

(n) Negligently assembling the Summit Tapered Hip System and its stem in a manner which was dangerous to its recipients;

(o) Concealing information regarding tests, and/or reports, and/or studies from the Plaintiff and her physicians, demonstrating that the Summit Tapered Hip System was unsafe, dangerous, and/or non-conforming with accepted industry standards;

(p) Improperly concealing information from and/or misrepresenting information to the Plaintiffs, health care professionals, hospitals and/or the FDA, concerning the severity of risks and dangers of the Summit Tapered Hip System and its stem;

(q) Failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the Summit Tapered Hip System and its stem; and

(r) Failing to provide reasonable assurance with respect to the safety and effectiveness of the Summit Tapered Hip System and its stem.

283. Defendants violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

284. Defendants under-reported, underestimated and downplayed the serious dangers of the Summit Tapered Hip System and its stem.

285. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Summit Tapered Hip System and its stem in that they:

(a) Failed to use due care in designing and manufacturing the Summit System so as to avoid the aforementioned risks to individuals when the Summit Tapered Hip System and its stem were used in total hip replacement surgeries;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the Summit Tapered Hip System;

(c) Failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the Summit Tapered Hip System and its stem;

(d) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(e) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Summit Tapered Hip System and its stem;

(f) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA prior to actively encouraging the sale of the Summit Tapered Hip System, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(g) Were otherwise careless or negligent.

286. Defendants knew or should have known that consumers such as the Plaintiff would suffer foreseeable injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

287. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence *per se*.

288. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss which she suffered and/or will continue to suffer.

289. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

290. By reason of the foregoing, plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

SECOND CAUSE OF ACTION AS AGAINST THE DEPUY DEFENDANTS (STRICT PRODUCTS LIABILITY)

291. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

292. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed the Summit Tapered Hip System as herein above described and Plaintiff was a recipient of said product.

293. The Summit Tapered Hip System was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed

by the Defendants.

294. At all relevant times, the Summit Tapered Hip System and its stem were in an unsafe, defective, and inherently dangerous condition, which was dangerous to recipients, and in particular, the Plaintiff herein.

295. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the Summit Tapered Hip System.

296. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary healthcare provider would expect.

297. At all times herein mentioned, the Summit Tapered Hip System and its stem were in a defective condition and unsafe, and Defendants knew, or had reason to know, that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

298. Defendants knew, or should have known, that at all times herein mentioned, the Summit Tapered Hip System and its stem were in a defective condition, and was inherently dangerous and unsafe.

299. At the time of the Plaintiff's receipt and/or use of the Summit Tapered Hip System, the Summit System and stem was being used for the purposes and in a manner normally intended, namely as a total hip replacement system.

300. Defendants, with this knowledge, voluntarily designed the Summit Tapered Hip

System and its stem in a dangerous condition for use by the public, and in particular the plaintiff and/or her health care professionals.

301. Defendants had a duty to create a product that was not unreasonably dangerous or its normal, intended use.

302. Defendants created a product unreasonably dangerous for its normal, intended use.

303. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was manufactured defectively in that said Summit Tapered Hip System left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

304. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Summit Tapered Hip System and stem was manufactured.

305. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and defendants are therefore strictly liable for the injuries sustained by the plaintiff.

306. The Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

307. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a risk of unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and

permanent health consequences, and the Defendants failed to adequately warn of said risk.

308. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings and/or inadequate testing.

309. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and defendants failed to provide adequate warnings to users or consumers of the product, and continued to promote the product.

310. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, the Summit Tapered Hip System and its stem.

311. Defendants' defective design, manufacturing defect, and inadequate warnings of the Summit Tapered Hip System and its stem were acts that amount to willful, wanton, and/or reckless conduct by defendants.

312. That said defects in Defendants' Summit Tapered Hip System and it stem were substantial factors in causing plaintiff s injuries.

313. As a result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greater increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

314. As a result of the foregoing acts and omissions, the Plaintiff, Mrs Rouviere requires and will require health care and services, and did incur medical, health, incidental and

related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

315. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

THIRD CAUSE OF ACTION AS AGAINST THE DEPUY DEFENDANTS (BREACH OF EXPRESS WARRANTY)

316. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

317. Defendants expressly warranted that the Summit Tapered Hip System and stem were safe and/or well accepted by users.

318. The Summit Tapered Hip System and stem does not conform to these express representations because the Summit Tapered Hip System and stem is not safe and has numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

319. Plaintiff did rely on the express warranties of the Defendants herein.

320. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the defendants for use of the Summit Tapered Hip System and stem in total hip replacement surgeries.

321. Defendants herein breached the aforesaid express warranties, as their Summit Systems and stem were defective.

322. Defendants expressly represented to the users, their physicians, healthcare providers, and/or the FDA that the Summit Tapered Hip System and stem were safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any

dangerous side effects, and that it was adequately tested and fit for its intended use.

323. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Summit Tapered Hip System and stem was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

324. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

325. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

326. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction; over this action.

FOURTH CAUSE OF ACTION AS AGAINST THE DEPUY DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

327. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

328. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold the Summit System and stem, which is used in total hip replacement surgeries. At the time defendants marketed, sold, and distributed the Summit Tapered Hip System for use by Plaintiff, Defendants knew of the use for which the Summit Tapered Hip System and stem was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

329. Defendants impliedly represented and wan-anted to the users and their physicians, healthcare providers, and/or the FDA that the Summit Tapered Hip System and stem was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

330. That said representations and warranties aforementioned were false, misleading and inaccurate in that the Summit Tapered Hip System and stem was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

331. Plaintiff, and members of the medical community, did rely on said implied warranties of merchantability and/or fitness for a particular use and purpose.

332. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of defendants as to whether the Summit Tapered Hip System and stem was of merchantable quality and safe and fit for its intended use.

333. The Summit Tapered Hip System stem was injected into the stream of commerce by the defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

334. Defendants herein breached the aforesaid implied warranties, as their Summit System was not fit for its intended purposes and uses.

335. As a result of the foregoing acts and omissions, Plaintiff was, and/or still is, caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

336. As a result of the foregoing acts and omissions, plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain

further medical and/or hospital care, attention, and services.

337. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS STRYKER (NEGLIGENCE AND NEGLIGENCE PER SE)

338. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

339. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, supplying, promoting, packaging, sale and/or distribution of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

340. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System into the interstate commerce in that Defendants knew or should have known that using the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System created a high risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

341. The negligence of the defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Designing and manufacturing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System without thoroughly testing it;

(b) Not conducting sufficient testing programs to determine whether or not the aforesaid "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was safe for use; in that defendants knew or should have known that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unsafe and unfit for use by reason of the

dangers to recipients;

(c) Selling the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System without making proper and sufficient tests to determine the dangers to recipients;

(d) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ;

(e) Negligently failing to recall their dangerous and defective "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System at the earliest date that it became known that said systems were, in fact, dangerous and defective;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ;

(g) Failing to test the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and/or failing to adequately, sufficiently and properly test the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ;

(h) Negligently advertising and recommending the use of the aforesaid "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System had equivalent safety and efficacy as other, non defective

total hip replacement systems;

(k) Negligently designing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a manner which was dangerous to its recipients;

(l) Negligently manufacturing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a manner which was dangerous to its recipients;

(m) Negligently producing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a manner which was dangerous to its users;

(n) Negligently assembling the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its stem in a manner which was dangerous to its recipients;

(o) Concealing information regarding tests, and/or reports, and/or studies from the Plaintiff and her physicians, demonstrating that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unsafe, dangerous, and/or non-conforming with accepted industry standards;

(p) Improperly concealing information from and/or misrepresenting information to the Plaintiffs, health care professionals, hospitals and/or the FDA, concerning the severity of risks and dangers of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ;

(q) Failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ; and

(r) Failing to provide reasonable assurance with respect to the safety and effectiveness of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

342. Defendants violated statutes, rules and ordinates concerning the manufacturing,

marketing, and/or testing of their product.

343. Defendants under-reported, underestimated and downplayed the serious dangers of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System

344. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in that they:

(a) Failed to use due care in designing and manufacturing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System so as to avoid the aforementioned risks to individuals when the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were used in total hip replacement surgeries;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ;

(c) Failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(d) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(e) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ;

(f) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA prior to actively encouraging the sale of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System ,either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(g) Were otherwise careless or negligent.

345. Defendants knew or should have known that consumers such as the Plaintiff would suffer foreseeable injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

346 . Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence *per se*.

347. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss which she suffered and/or will continue to suffer.

348. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

349. By reason of the foregoing, plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

SIXTH CAUSE OF ACTION AS AGAINST THE STRYKER DEFENDANTS (STRICT PRODUCTS LIABILITY)

350. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

351. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System as hereinabove described and Plaintiff was a recipient of said product.

352. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

353. At all relevant times, the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were in an unsafe, defective, and inherently dangerous condition, which was dangerous to recipients, and in particular, the Plaintiff herein.

354. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

355. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary healthcare provider would expect.

324. At all times herein mentioned, the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were in a defective condition and unsafe, and Defendants knew, or had

reason to know, that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

356. Defendants knew, or should have known, that at all times herein mentioned, the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were in a defective condition, and was inherently dangerous and unsafe.

357. At the time of the Plaintiff's receipt and/or use of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was being used for the purposes and in a manner normally intended, namely as a total hip replacement system.

358. Defendants, with this knowledge, voluntarily designed the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a dangerous condition for use by the public, and in particular the plaintiff and/or her health care professionals.

359. Defendants had a duty to create a product that was not unreasonably dangerous or its normal, intended use.

360. Defendants created a product unreasonably dangerous for its normal, intended use.

361. MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was manufactured defectively in that said MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

362. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and stem was manufactured.

363. Defendants designed, researched, manufactured, tested, advertised, promoted,

marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and defendants are therefore strictly liable for the injuries sustained by the plaintiff.

364. The Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

365. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a risk of unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and the Defendants failed to adequately warn of said risk.

366. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings and/or inadequate testing.

367. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and defendants failed to provide adequate warnings to users or consumers of the product, and continued to promote the product.

368. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective

product, the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System .

369. Defendants' defective design, manufacturing defect, and inadequate warnings of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were acts that amount to willful, wanton, and/or reckless conduct by defendants.

370. That said defects in Defendants' MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were substantial factors in causing plaintiff s injuries.

371. As a result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greater increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

372. As a result of the foregoing acts and omissions, the Plaintiff, Mrs Rouviere requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

373. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

SEVENTH CAUSE OF ACTION AS AGAINST THE STRYKER DEFENDANTS (BREACH OF EXPRESS WARRANTY)

374. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

375. Defendants expressly warranted that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and stem were safe and/or well accepted by users.

376. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System

does not conform to these express representations because the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and stem is not safe and has numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

377. Plaintiff did rely on the express warranties of the Defendants herein.

378. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the defendants for use of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in total hip replacement surgeries.

379. Defendants herein breached the aforesaid express warranties, as their MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were defective.

380. Defendants expressly represented to the users, their physicians, healthcare providers, and/or the FDA that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

381. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

382. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

383. As a result of the foregoing acts and omissions, the Plaintiff requires and will

require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

384. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction; over this action.

EIGTH CAUSE OF ACTION AS AGAINST THE STRYKER DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

385. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

386. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , which is used in total hip replacement surgeries. At the time defendants marketed, sold, and distributed the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System for use by Plaintiff, Defendants knew of the use for which the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

387. Defendants impliedly represented and wan-anted to the users and their physicians, healthcare providers, and/or the FDA that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

388. That said representations and warranties aforementioned were false, misleading and inaccurate in that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM

System was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

389. Plaintiff, and members of the medical community, did rely on said implied warranties of merchantability and/or fitness for a particular use and purpose.

390. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of defendants as to whether the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was of merchantable quality and safe and fit for its intended use.

391. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was injected into the stream of commerce by the defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

392. Defendants herein breached the aforesaid implied warranties, as their MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was not fit for its intended purposes and uses.

393. As a result of the foregoing acts and omissions, Plaintiff was, and/or still is, caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

394. As a result of the foregoing acts and omissions, plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

395. By reason of the foregoing, Plaintiff has been damaged as against the Defendants

in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

NINTH CAUSE OF ACTION AS AGAINST THE STRYKER & DEPUY - HUSBAND ANDRE ROUVIERE'S CLAIM FOR LOSS OF CONSORTIUM

396. Plaintiff repeats, reiterates and re alleges each and every allegations included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, and specifically re alleges and re adopts all previous eight causes of action with the same force and effect as if more fully set forth herein.

397. At the time of the acts as plead in this the Plaintiffs' Complaint, the Plaintiffs were married and that the Plaintiffs continue to be married.

398. That as a result of the wrongful and negligent, and deliberate acts of the Defendants, and each of them, the Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

399. That all the injuries and damages were caused solely and proximately by the negligence of the Depuy and Stryker Defendants .

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

a. Awarding plaintiff actual damages incidental to plaintiffs use of the defendants' Defective Devices in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to plaintiff;

c. Awarding pre-judgment and post-judgment interest to

plaintiff;

d. Awarding the costs and expenses of this litigation to plaintiff;

e. Awarding reasonable costs to plaintiffs as provided by law;

f. Granting all such other, further and/or different relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands trial by jury on all issues so triable.

JODI ROUVIERE, PRO SE Plaintiff
4070 Laguna Street,
Coral Gables, Florida 33146
305 608 8076

ANDRE ROUVIERE, PRO SE Plaintiff
4070 Laguna Street,
Coral Gables, Florida 33146
305 790 9325

FedEx carbon-neutral
envelope shipping

Express

ORIGIN ID:JDMA (305) 790-9325
ANDRE ROUVIERE

4070 LAGUNA ST

CORAL GABLES, FL 33146
UNITED STATES US

SHIP DATE: 29MAY18
ACTWGT: 0.80 LB
CAD: 6991365/SSF01904

BILL CREDIT CARD

TO DANIEL PATRICK MOYNIHAN U.S
DISTRICT COURT PRO SE INTAKE UNIT
500 PEARL ST ROOM 200

NEW YORK NY 10007
(000) 000-0000 REF:
INV:
PO: DEPT:

FedEx
Express

E

WED - 30 MAY 3:00P
STANDARD OVERNIGHT

TRK# 0201 7811 7225 6470

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